

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

APOTEX, INC.,

Plaintiff

v.

CEPHALON, INC., et al.

Defendants

CIVIL ACTION

No. 2:06-cv-2768

DECLARATION OF SADAF R. ABDULLAH
IN SUPPORT OF DEFENDANT CEPHALON, INC.'S MOTION *IN LIMINE* TO
PRECLUDE APOTEX INC. FROM RELYING ON LATE-PRODUCED DOCUMENTS
RELATING TO APOTEX'S STANDARD OPERATING PROCEDURES

(Redacted Version)

March 7, 2011

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Attorneys for Defendant Cephalon, Inc.

I, Sadaf R. Abdullah, hereby declare and state as follows:

1. I am an attorney admitted and in good standing with the Massachusetts Bar and the New York Bar and an attorney at the law firm of Wilmer Cutler Pickering Hale and Dorr LLP, counsel for Defendant Cephalon, Inc. I make this Declaration in support Defendant Cephalon, Inc.'s Motion *In Limine* To Preclude Apotex Inc. From Relying On Late-Produced Documents Relating To Apotex's Standard Operating Procedures.
2. Attached as Exhibit 1 are true and correct copies of excerpts of Apotex Inc.'s Abbreviated New Drug Application ("ANDA") produced by Apotex Inc. in this litigation, **filed under seal.**
3. Attached as Exhibit 2 is a true and correct copies of Defendant Cephalon's First Set of Requests for Production.
4. Attached as Exhibit 3 are true and correct copies of excerpts from the Deposition of Anna Chow taken on July 20, 2010, **filed under seal.**
5. Attached as Exhibit 4 is a true and correct copy of a document entitled "Standard Operating Procedure: Sampling & Inspection of Incoming Materials" dated July 20, 2004, bearing the Bates stamps AI0089072-9085, and produced by Apotex Inc. on November 30, 2010, **filed under seal.**

March 7, 2011

/s/ Sadaf R. Abdullah

Sadaf R. Abdullah
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EXHIBIT 1
FILED UNDER SEAL

EXHIBIT 2

**IN THE UNITED STATES DISTRICT COURT
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APOTEX, INC.,

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**DEFENDANT CEPHALON, INC.'S FIRST REQUEST FOR PRODUCTION OF
DOCUMENTS AND THINGS TO PLAINTIFF APOTEX, INC.**

Pursuant to Fed.R.Civ.P. 34, defendant Cephalon, Inc. requests that plaintiff Apotex, Inc. ("Apotex") produce the following documents and things for inspection and copying at the offices of Conrad O'Brien, P.C., 1515 Market Street, 16th Floor, Philadelphia, PA 19102, within thirty (30) days of service of these requests.

DEFINITIONS AND INSTRUCTIONS

A. The term "document" as used in this Request is synonymous in meaning and equal in scope to this term as used in Fed.R.Civ.P. 34(a) and includes, without limitation, tangible things and any information-containing paper or other medium or materials whether handwritten, printed, recorded, filmed, or produced by any other mechanical, chemical or electronic process, including e-mail, whether or not asserted to be privileged or immune from discovery, and whether a draft, original, or copy, including any notes or marginal notations appearing on any document, including self-stick removable notes.

B. "Cephalon" means the defendant, Cephalon, Inc., and its employees, agents, representatives, and assigns.

C. "Apotex" means the plaintiff Apotex, Inc., and any and all predecessors, successors, divisions, subsidiaries, or joint ventures thereof, together with any and all parent or affiliated companies or corporations, and all officers, directors, employees, agents, attorneys, representatives, and all other persons acting or purporting to act or that have acted or purported to have acted on behalf of any of the foregoing.

D. The "RE '516 patent" means U.S. Reissue Patent No. RE 37,516, and any continuations, continuations-in-part, divisions, and foreign counterparts thereof, and any applications, prosecutions, or proceedings related to any of the foregoing.

E. The "'346 patent" means U.S. Patent No. 7,297,346 and any continuations, continuations-in-part, divisions, and foreign counterparts thereof, and any applications, prosecutions, or proceedings related to any of the foregoing.

F. "Apotex ANDA" means Abbreviated New Drug Application No. 77-667, submitted to the United States Food and Drug Administration ("FDA") by Apotex.

G. "Apotex Notice Letters" means all Paragraph III and IV notice letters that Apotex sent to Cephalon regarding Apotex's ANDA.

H. "Apotex ANDA Modafinil Tablets" means any Apotex modafinil product described in the Apotex ANDA.

I. "Apotex Modafinil API" means any active pharmaceutical ingredient used in manufacturing the Apotex ANDA Modafinil Tablets.

J. "Person" means any natural person or any business, legal, or governmental entity or association and the officers, directors, employees, agents, and attorneys thereof.

K. The terms "related to" and "relating to" include "refer to," "summarize," "reflect," "constitute," "contain," "embody," "mention," "show," "comprise," "evidence," "discuss," "describe," and "comment upon."

L. The words "and" and "or" shall be construed conjunctively or disjunctively, whichever makes the request more inclusive, and "any" shall mean each and every.

M. "Concerning" shall mean referring to, describing, evidencing, or constituting.

N. If Apotex contends that any document requested to be produced is protected from discovery by the attorney-client privilege, work product immunity, or some other privilege or immunity, please identify each such document with at least the following information:

- (1) a description of the type of document, i.e., "letter," "memorandum," "report," "miscellaneous note," etc.;
- (2) the date, and if no date appears thereon, the date or approximate date upon which the document was prepared;
- (3) the name of the person(s) who signed the document and the name of the person or persons who prepared the document if different from the signers;
- (4) the organization, if any, with which each signer or preparer was then connected;
- (5) the names and addresses of all recipients;
- (6) the names and addresses of all other persons to whom the document was distributed;
- (7) the names and addresses of all attorneys involved in the preparation or receipt of document, if the attorney-client privilege or work product immunity is claimed as

to the document;

- (8) a brief description of the subject matter; and
- (9) a statement of the grounds for refusal to produce the document.

DOCUMENTS TO BE PRODUCED

REQUEST NO. 1

A copy of the Apotex ANDA, including all amendments, exactly as filed with the FDA with all accompanying exhibits, figures, drawings, charts, graphs, data, appendices, attachments, drug master files, and enclosures.

REQUEST NO. 2

All documents relating or referring to the Apotex ANDA and any amendments thereto, including any and all drafts thereof.

REQUEST NO. 3

All drug master files for the active pharmaceutical ingredient ("API") used for, or intended to be used for, the manufacturing of Apotex ANDA Modafinil Tablets.

REQUEST NO. 4

All ANDA records, including all amendments, relating to the facilities at which Apotex Modafinil API and/or the Apotex ANDA Modafinil Tablets and/or any other Apotex modafinil product will be or are expected to be manufactured.

REQUEST NO. 5

All documents, reports or correspondence to, from or with any governmental or regulatory agency, including but not limited to the FDA and Health Canada relating to Good Manufacturing Practices ("GMP"), inspections, manufacturing, or quality control or assurance

issues experienced at any facility wherein Apotex Modafinil API or Apotex ANDA Modafinil Tablets or any other Apotex modafinil product will be or are expected to be manufactured or produced. This request includes, without limitation, all warning letters, notices and/or inspectional documents, FDA Establishment Inspection Reports ("EIRs") and/or Forms FDA-483 ("FDA-483s") issued for each site or facility identified above, from January 1, 2000, to the date of this request.

REQUEST NO. 6

All documents relating to the Apotex ANDA Modafinil Tablets.

REQUEST NO. 7

All submissions to or communications with the FDA relating to the Apotex ANDA, any amendments thereto, any amended or supplemental drug master files, and/or the Apotex ANDA Modafinil Tablets.

REQUEST NO. 8

To the extent not produced in response to any other Request for Production, all correspondence with the FDA or any other regulatory body or agency relating to any deficiency or problem with the Apotex ANDA or any other requested generic marketing authorization or approval related to modafinil.

REQUEST NO. 9

All documents relating to any substance, product, or embodiment containing modafinil that has been made, used, sold, or offered for sale by any person.

REQUEST NO. 10

All documents comprising or concerning the decision to file the Apotex ANDA or any amendments thereto, including without limitation documents concerning the Apotex ANDA

project proposals and approvals, patent invalidity, freedom-to-operate, clearance or infringement reviews or investigations, and FDA investigations with respect to the Apotex ANDA Modafinil Tablets.

REQUEST NO. 11

All documents relating to the licensing of any Apotex ANDA Modafinil Tablets or any technology incorporated in any Apotex ANDA Modafinil Tablets.

REQUEST NO. 12

All documents comprising or concerning the decision to develop, manufacture, and sell Apotex ANDA Modafinil Tablets, including without limitation documents concerning drug and compound reviews, business plans, pricing strategies, regulatory plans, product or project proposals and approvals, meeting minutes, patent invalidity, freedom to operate, clearance or infringement reviews or investigations, strategic plans or forecasts, market studies, market projection or forecasts, marketing plans, manufacturing strategies and agreements, distribution strategies and agreements, and competitive analyses with respect to the Apotex ANDA Modafinil Tablets.

REQUEST NO. 13

All documents related to the manufacturing of the Apotex ANDA Modafinil Tablets, including amounts manufactured or planned to be manufactured, manufacturing agreements, amounts distributed or planned to be distributed, and distribution agreements.

REQUEST NO. 14

All documents showing Apotex's anticipated, forecasted, or projected sales and market share of its Apotex ANDA Modafinil Tablets.

REQUEST NO. 15

All documents related to any research or forecasting performed by Apotex or at the direction of Apotex as to the effect of branded product sales upon the launch of a generic drug.

REQUEST NO. 16

All documents relating to the prosecution, infringement, non-infringement, validity, invalidity, enforceability, or unenforceability of the RE '516 patent.

REQUEST NO. 17

All documents relating to the prosecution, infringement, non-infringement, validity, invalidity, enforceability, or unenforceability of the '346 patent.

REQUEST NO. 18

All documents concerning, referring, or relating to prior art to the RE '516 patent or any search thereof.

REQUEST NO. 19

All documents concerning, referring, or relating to prior art to the '346 patent or any search thereof.

REQUEST NO. 20

All documents relating to any contention that the making, using, importing, selling, or offering for sale of any Apotex ANDA Modafinil Tablets or any other modafinil tablets in the United States would not infringe the RE '516 patent.

REQUEST NO. 21

All documents relating to any contention that the making, using, importing, selling, or offering for sale of any Apotex ANDA Modafinil Tablets or any other modafinil tablets in the United States would not infringe the '346 patent.

REQUEST NO. 22

All documents relating to the conception, design, engineering, development, testing, manufacture, production, marketing, pricing strategy, regulatory approval, or sale of the Apotex ANDA Modafinil Tablets.

REQUEST NO. 23

All documents concerning or referring to Provigil®.

REQUEST NO. 24

To the extent not requested above, all documents concerning Cephalon, the Apotex ANDA, the Apotex ANDA Modafinil Tablets, or the subject matter of the instant litigation.

REQUEST NO. 25

Documents sufficient to show the organizational structure of Apotex over the last five (5) years, including without limitation organizational charts and personnel lists for each team, group, or division having anything to do with studying, researching, designing, developing, producing, marketing, or seeking regulatory approval for any Apotex ANDA Modafinil Tablets or modafinil-containing substance.

REQUEST NO. 26

All documents prepared by or for Apotex for the purpose of raising money or capital, or for making a public offering, which refer to the Apotex ANDA, Apotex ANDA Modafinil Tablets, or Cephalon.

REQUEST NO. 27

Documents sufficient to show Apotex's research and development expenditures, if any, for developing Apotex's ANDA Modafinil Tablets.

REQUEST NO. 28

Documents sufficient to show Apotex's annual research and development

expenditures for each year from the time Apotex decided to develop Apotex's ANDA Modafinil Tablets until the present.

REQUEST NO. 29

All documents relating to the manner in which the Apotex ANDA Modafinil Tablets function, or can function, to treat: excessive daytime or shift-work-related sleepiness, sleepiness associated with narcolepsy or sleep apnea, sleepiness or fatigue associated with depression or other clinical disorders, ADD, ADHD, or other attention deficit disorders.

REQUEST NO. 30

All documents relating to any testing of the Apotex ANDA Modafinil Tablets.

REQUEST NO. 31

All documents comparing, or addressing the characteristics or relative merits of, any modafinil-containing substance with the Apotex ANDA Modafinil Tablets or any other Apotex product containing modafinil.

REQUEST NO. 32

All documents referring or relating to any clinical trials or studies of modafinil conducted by, or on behalf of, Apotex.

REQUEST NO. 33

All documents referring or relating to any failure, shortcoming, or performance deficiency of the Apotex ANDA Modafinil Tablets.

REQUEST NO. 34

All documents referring or relating to the design or development of the Apotex ANDA Modafinil Tablets, including without limitation engineering notebooks, laboratory notebooks, electronic laboratory notebooks, scientists' individual notes, meeting minutes, meeting agendas,

laboratory reports, test results, internal memoranda, correspondence, articles, or other publications.

REQUEST NO. 35

Twenty (20) GMP-compliant 100 mg tablets, meeting all specifications for the product described in the Apotex ANDA and capable of being offered for sale or sold in the United States upon final approval of the Apotex ANDA, taken from five (5) different batches where the batch numbers are identified for each set of five tablets, one hundred (100) 100 mg tablets in total, and five (5) grams of GMP-compliant active pharmaceutical ingredient ("API") for each identified batch of tablets, five (5) five-gram API samples in total. All tablets and API shall be manufactured within the proposed or established expiration or retest date for which Apotex has generated appropriate stability data. The tablets shall be produced in the packaging (blister-packs or bottle containers) in which they would be distributed or supplied in ordinary commerce. The API samples shall be obtained from each bulk batch via a rotary sample divider, sometimes referred to as a riffler. Stationary sampling, such as the use of a spatula or thief, shall not be utilized. The sampling via a rotary sample divider shall be performed by Cephalon's expert at Apotex's facility under the observation of a representative of Apotex, or shall be videotaped and observed by an Apotex expert or employee knowledgeable of sampling techniques for particle size measurement, who shall be made available to Cephalon's counsel for deposition.

REQUEST NO. 36

Twenty (20) GMP-compliant 200 mg tablets, meeting all specifications for the product described in the Apotex ANDA and capable of being offered for sale or sold in the United States upon final approval of the Apotex ANDA, taken from five (5) different batches where the batch numbers are identified for each set of five tablets, one hundred (100) 200 mg tablets in total, and

five (5) grams of GMP-compliant active pharmaceutical ingredient (“API”) for each identified batch of tablets, five (5) five-gram API samples in total. All tablets and API shall be manufactured within the proposed or established expiration or retest date for which Apotex has generated appropriate stability data. The tablets shall be produced in the packaging (blister-packs or bottle containers) in which they would be distributed or supplied in ordinary commerce. The API samples shall be obtained from each bulk batch via a rotary sample divider, sometimes referred to as a riffler. Stationary sampling, such as the use of a spatula or thief, shall not be utilized. The sampling via a rotary sample divider shall be performed by Cephalon's expert at Apotex's facility under the observation of a representative of Apotex, or shall be videotaped and observed by an Apotex expert or employee knowledgeable of sampling techniques for particle size measurement, who shall be made available to Cephalon's counsel for deposition.

REQUEST NO. 37

Samples of all modafinil products manufactured by Apotex or purchased by Apotex from any other entity.

REQUEST NO. 38

All documents relating to any efforts of Apotex to design around or circumvent the RE '516 patent, the '346 patent or any other Cephalon patent, including copies of any Cephalon patents consulted by Apotex in formulating the Apotex Modafinil API or the Apotex ANDA Modafinil Tablets.

REQUEST NO. 39

All documents relating to the Apotex Notice Letters, including but not limited to documents relating to the process by which Apotex decided to file and send the Apotex Notice

Letters to Cephalon and the decision by Apotex to convert its original Paragraph III notice letter to a Paragraph IV notice letter.

REQUEST NO. 40

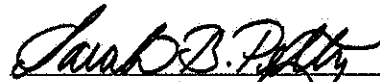
All documents relating to the particle size of Apotex's Modafinil API, including any particle size measurements of Apotex's Modafinil API conducted by Apotex or any other entity, including all documents relating to any protocol(s) for particle size measurement used to measure the particle size distribution of the Apotex Modafinil API.

REQUEST NO. 41

All documents relating to the importation into, presence and/or amount in inventory of any Apotex ANDA Modafinil Tablets in the United States, including any correspondence with or authorizations or prohibitions issued by U.S. Customs or FDA regarding same.

Dated: March 16, 2010

Respectfully submitted,



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Plaintiff,

v.

CEPHALON INC., et al.,

Defendants.

CIVIL ACTION

No. 06-2768 MSG

CERTIFICATE OF SERVICE

Pursuant to paragraph 21 of the February 19, 2010 Scheduling Order, I certify that on the date set forth below Defendant Cephalon, Inc.'s First Request for Production of Documents and Things to Plaintiff Apotex, Inc. was served by e-mail on the persons identified below:

<p>Brian J. Sodikoff, Esquire Katten, Muchin, Rosenmann, LLP 525 West Monroe Street Chicago, IL 60661-3693 Email: brian.sodikoff@kattenlaw.com Attorneys for Apotex, Inc.</p>	<p>Karen N. Walker, Esquire Kirkland & Ellis LLP 655 Fifteenth Street, N.W. Washington, D.C. 20005 Email: kwalker@kirkland.com Discovery Counsel for Generic Defendants</p>
<p>Howard I. Langer, Esquire Langer & Grogan P.C. 1717 Arch Street Suite 4130 Philadelphia, PA 19103 Email: hlanger@langergrogan.com</p>	<p>Joseph Opper, Esquire Garwin Gerstein & Fisher LLP 1501 Broadway, Suite 1416 New York, NY 10036 Email: jopper@garwingerstein.com Discovery Counsel for Direct Purchasers</p>
<p>Saralisa C. Brau, Esquire Federal Trade Commission 601 New Jersey Ave. NW, Room 7225 Washington, DC 20001 Email: sbrau@ftc.gov Attorneys for Federal Trade Commission</p>	<p>Terence S. Ziegler, Esquire Barroway Topaz Kessler Meltzer & Check 280 King of Prussia Road Radnor, Pa 19087 email: tziegler@btkmc.com Discovery Counsel for Indirect Purchasers</p>

Notice of the filing of this Certificate of Service will be sent to all counsel of record by operation of the CM/ECF system.

Date: March 16, 2010

A handwritten signature in black ink, appearing to read "B. Betty", written over a horizontal line.

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

APOTEX, INC.,

Plaintiff,

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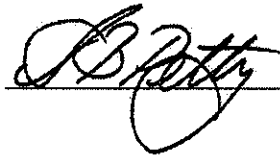
CERTIFICATE OF SERVICE

Pursuant to paragraph 21 of the February 19, 2010 Scheduling Order, I certify that on the date set forth below Defendant Cephalon, Inc.'s First Request for Production of Documents and Things to Plaintiff Apotex, Inc. was served by e-mail on the persons identified below:

<p>Brian J. Sodikoff, Esquire Katten, Muchin, Rosenmann, LLP 525 West Monroe Street Chicago, IL 60661-3693 Email: brian.sodikoff@kattenlaw.com Attorneys for Apotex, Inc.</p>	<p>Karen N. Walker, Esquire Kirkland & Ellis LLP 655 Fifteenth Street, N.W. Washington, D.C. 20005 Email: kwalker@kirkland.com Discovery Counsel for Generic Defendants</p>
<p>Howard I. Langer, Esquire Langer & Grogan P.C. 1717 Arch Street Suite 4130 Philadelphia, PA 19103 Email: hlanger@langergrogan.com</p>	<p>Joseph Oppen, Esquire Garwin Gerstein & Fisher LLP 1501 Broadway, Suite 1416 New York, NY 10036 Email: jopper@garwingerstein.com Discovery Counsel for Direct Purchasers</p>
<p>Saralisa C. Brau, Esquire Federal Trade Commission 601 New Jersey Ave. NW, Room 7225 Washington, DC 20001 Email: sbrau@ftc.gov Attorneys for Federal Trade Commission</p>	<p>Terence S. Ziegler, Esquire Barroway Topaz Kessler Meltzer & Check 280 King of Prussia Road Radnor, Pa 19087 email: tziegler@btkmc.com Discovery Counsel for Indirect Purchasers</p>

Notice of the filing of this Certificate of Service will be sent to all counsel of record by operation of the CM/ECF system.

Date: March 16, 2010

A handwritten signature in cursive script, appearing to read "Betty", is written over a horizontal line.

EXHIBITS 4 & 5
FILED UNDER SEAL